Award Number: W81XWH-14-2-0140

TITLE: Effects of Acoustic Impulses on the Middle Ear

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REPORT DATE: October 2017

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

Approved for public release; distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
October 2017	Annual	09/22/2016 – 9/21/2017

4. TITLE AND SUBTITLE
"Effects of Acoustic Impulses on the Middle Ear"

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-14-2-0140

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
The Geneva Foundation
917 Pacific Ave., Ste. 600
Tacoma, WA 98402

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S Army Medical Research and Materiel Command
Fort Detrick, MD 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
The objective of this project is to fully document the effects of acoustic impulses on the middle ear and on middle-ear muscle contractions (MEMC). This project will provide critical information on the middle ear musculature states during warned and unwarned exposures to acoustic impulses. This information necessary in the development of new (or revising existing) damage risk criteria and health hazard assessment methods for exposure to high-level acoustic impulses such as experienced by users of military and civilian law enforcement weapon systems, civilian recreational hunting and shooting, and industrial high-level impulsive noises (impacts and impulses).

15. SUBJECT TERMS None listed

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	UU	26	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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Introduction:

The objective of this project is to fully document the effects of acoustic impulses on the middle ear and on middle-ear muscle contractions (MEMC). This project will provide critical information on the middle ear musculature states during warned and unwarned exposures to acoustic impulses. This information is necessary to inform damage risk criteria and health hazard assessment methods for exposure to high-level acoustic impulses such as experienced by users of military and civilian law enforcement weapon systems, civilian recreational hunting and shooting, and industrial high-level impulsive noises (impacts and impulses).

Keywords:

Noise exposure; hearing loss, noise-induced; impulsive noise; reflex; conditioned response; middle ear; damage-risk criteria; health hazard evaluation

ACCOMPLISHMENTS:

What were the major goals of the project?
The major goals of the project as stated in the approved SOW are:

1. Determine the prevalence of acoustic reflexes among young people with H-1 hearing status as per Army Regulation 40-501, Table 7-1.
2. Determine whether reflexive MEMC are pervasive for multiple acoustic and non-acoustic stimuli.
3. Determine whether conditioned MEMC are pervasive, in either laboratory or field settings, and if so, identify differences between reflexive and conditioned MEMC.

What was accomplished under these goals?
Task 1: Determine the prevalence of acoustic reflexes among young people with H-1 hearing status as per Army Regulation 40-501, Table 7-1.

Major activities
The majority of the work associated with this task was completed during a previous project period, and dissemination is underway.

Significant results
Additional work was completed under this objective, assessing the proportion of clinical acoustic reflexes observed among participants tested at Western Michigan University as part of aims two and three of this project. Analysis were conducted and disseminated as a podium presentation and an invited manuscript in the *International Journal of Audiology* (currently under review). Results of this study, which used a diagnostic middle ear analyzer, were consistent with the previously reported results, i.e., that clinical acoustic reflexes are not pervasive.

Other achievements:
Nothing to report.

Task 2: Determine whether reflexive MEMC are pervasive for multiple acoustic and non-acoustic stimuli.

AND

Task 3: Determine whether MEMC can be classically conditioned with 95 % certainty in 95 % of people, either in laboratory or field settings, and if so, identify any differences between reflexive and conditioned MEMC.

Major activities
The major activities during this period followed our proposed timeline. Our primary accomplishments during this reporting period included initiating pilot and routine data collection and further developing the procedures for data management and review on those tasks.

With the exception of the shared efforts on dissemination, the work on these tasks differed across sites.

USAARL

Work at the USAARL site has largely focused on subject recruitment, data collection, and preliminary review.

Enrollment and Data Collection

The cumulative completion plot (Figure 1) indicates the rate of participant recruitment and data collection. Overall, subject recruitment and data collection has advanced steadily, and approached the goal of 59 complete V2 data sets at the end of FY 17. All participants are regular shooters, and are completing tasks comparable to the ST and DF conditions that we had planned to run at the WMU site.

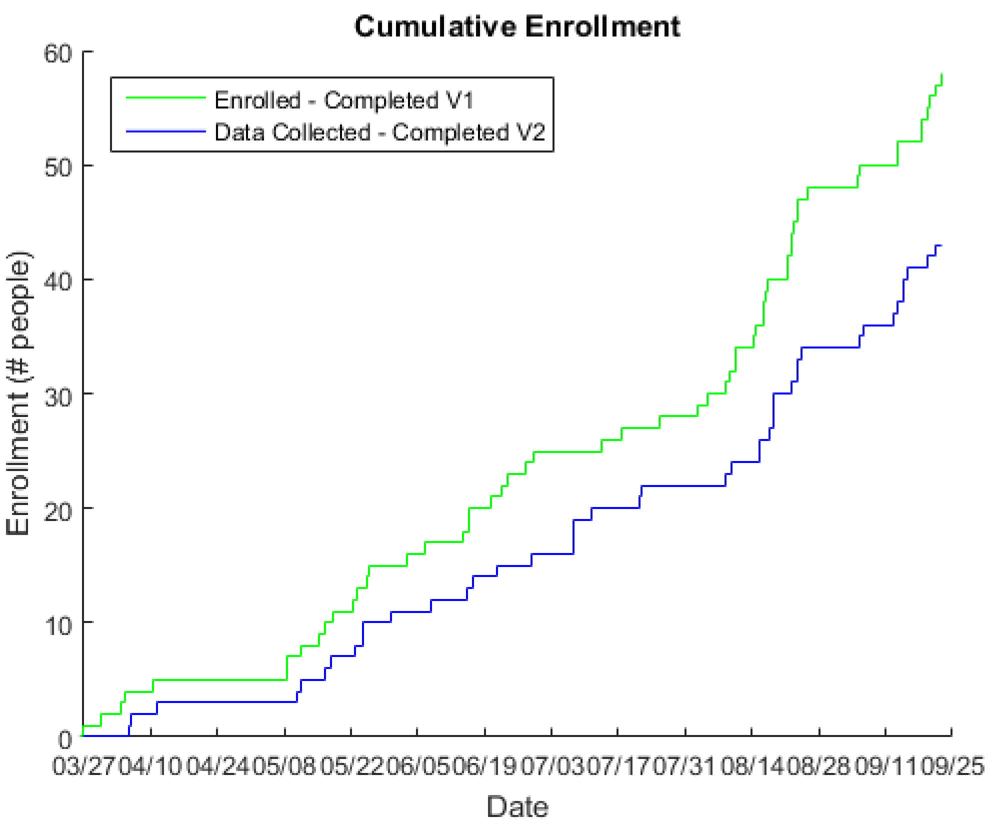


Figure 1. Cumulative Enrollment at USAARL

As of 22 September, 2017, 58 participants had enrolled and completed an enrollment visit (V1), and 43 subjects had completed the data collection visit (V2). A total of six subjects were dismissed after completing V1, the purpose of which is to assess candidacy. Five subjects withdrew after completing V1, and four subjects have V2 visits scheduled that have not yet been completed.

Data Analysis

Development of the data analysis tools continued during this study period. Progress details on the data analysis tools are presented in the SASRAC/WMU section below.

Development of Field Test Measurement Protocol

During this period, the human subject protocol at USAARL was amended to include the live-fire, field test measurements planned for the final phase of this project.

SASRAC/WMU
Work at the WMU site ended in March, and continued through SASRAC.

Participant demographics

Data collection at the WMU site was completed on March 20, 2017. There were 312 participants initially scheduled, and of those, 287 (92%) completed the first visit (V1) of the protocol (Figure 2). Twenty-four individuals were lost to follow up prior to signing the informed consent document and one volunteer completed informed consent, but was lost to follow up prior to completing V1. No participants declined to participate after the study was described during the informed consent process. The results of V1 were used to evaluate participant candidacy, and 82 (29%) participants did not meet the criteria to complete the study. A total of 197 participants completed V2. Six participants (3 % of the participants completing the first visit) were lost to follow up prior to their second appointment, and one person withdrew from the study for personal reasons prior to completing V2. One participant was unable to complete the conditioned task and did not complete V2.

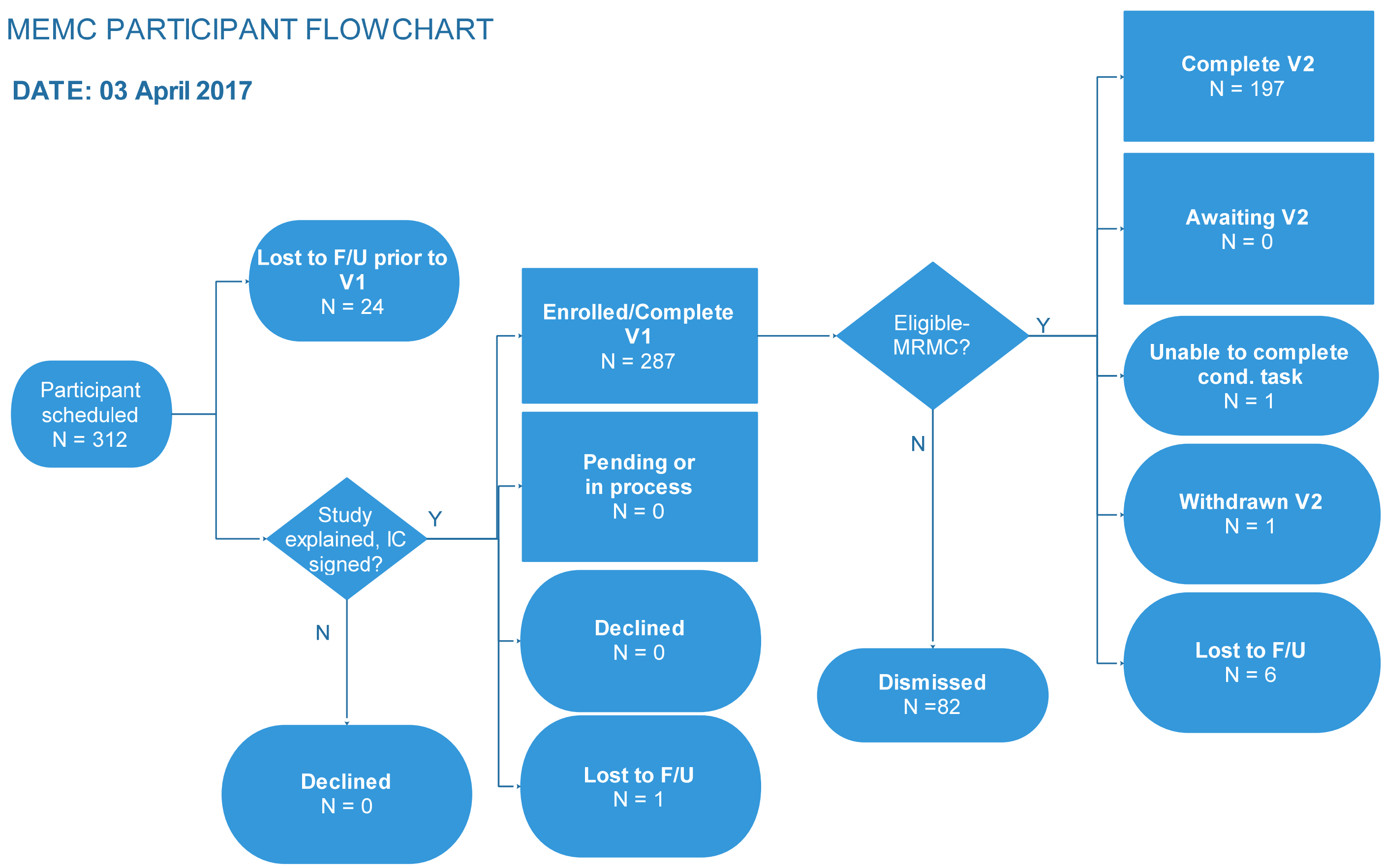


Figure 2: Final participant flowchart, WMU site.

Gender/Age

The median age of the participants in the study was 21 years old (interquartile range: 20 to 23 years). Participants included 201 (70%) females and 86 males. Both the young age of participants and the large number of female participants likely resulted from the location where participants were recruited. The fields of study at the College of Health and Human Services (CHHS) at Western Michigan University (WMU) are primarily dominated by young adult females.

Pure tone threshold results

Multiple levels of data review and analysis were completed using custom MATLAB functions and Stata v.15. Pure tone threshold results, obtained during V1, were analyzed for participants who were eligible and completed V2 (Table 1) and for participants who did not qualify to take part in the study based on their results from V1 (Table 2). In general, participants who were eligible for and completed V2 exhibited excellent hearing levels, with the 50th percentile thresholds at 0 dB HL in both ears and at all frequencies with the exception of 250 Hz in the right ear (2.5 dB HL) and 8 kHz in both ears (5 dB HL). Pure tone thresholds for participants who were dismissed from the study (Table 2) were generally good, but showed considerably more variability as a number of these individuals (n=52) were dismissed from the study because their pure tone thresholds did not meet the inclusion criteria. Participants who did not meet candidacy to take part in the study were also dismissed for a variety of reasons not relating to pure tone thresholds, and sometimes for more than one reason, including history of doctor-diagnosed concussion (n=17), lack of clinical acoustic reflexes (n=25), and history of Bell's Palsy (n=1).

Mean results from the eight individuals who were eligible but did not complete V2 for reasons stated above were within one standard deviation of the mean results from the participants who were eligible to take part in the study and completed V2 (Table 1) for all frequencies in both ears.

Table 1. Pure tone thresholds in dB HL, obtained at V1, for eligible participants who completed V2.

Hz	125	250	500	1k	2k	3k	4k	6k	8k
Left ear									
min	-10	-10	-10	-10	-10	-15	-15	-15	-10
p10	-5	-5	-5	-5	-5	-10	-10	-5	-5
p25	0	0	-5	-5	-5	-5	-5	-5	0
p50	0	0	0	0	0	0	0	0	5
p75	5	5	5	5	5	5	0	5	10
p90	5	5	5	5	10	5	5	10	15
max	10	10	10	10	20	15	20	15	20
mean	2	0	0	0	1	-1	-1	1	4
sd	4	4	4	5	5	6	6	6	7
Right ear									
min	-5	-10	-10	-10	-10	-15	-15	-15	-10
p10	0	-5	-5	-5	-5	-5	-10	-5	-5
p25	0	0	-5	-5	0	-5	-5	-5	0
p50	2.5	0	0	0	0	0	0	0	5
p75	5	5	5	5	5	5	0	5	10
p90	5	5	10	5	10	10	5	10	15
max	10	10	10	10	20	20	15	20	20
mean	3	1	1	0	2	1	-1	1	5
sd	4	4	5	5	5	6	5	6	7

Table 2. Pure tone thresholds in dB HL, obtained at V1, for participants who did not qualify to complete the study.

Hz	125	250	500	1k	2k	3k	4k	6k	8k
Left ear									
min	-10	-5	-5	-5	-10	-10	-10	-10	-10
p10	-5	-5	-5	-5	-5	-5	-5	-5	0
p25	0	0	0	0	0	-5	-5	0	5
p50	5	5	5	5	5	5	2.5	5	15
p75	10	10	10	10	15	10	10	15	25
p90	15	15	20	20	25	25	35	35	45
max	50	45	40	40	35	70	70	65	70
mean	6	6	6	5	8	7	8	11	17
sd	9	9	10	10	11	15	16	16	16
Right ear									
min	-5	-5	-5	-10	-5	-10	-10	-10	-10
p10	0	-5	-5	-5	-5	-5	-5	-5	0
p25	0	0	0	0	0	0	0	0	5
p50	5	5	5	5	5	5	0	5	12.5
p75	10	10	10	10	10	10	5	15	25
p90	15	15	15	15	15	20	25	30	40
max	45	40	25	25	30	45	50	45	60
mean	6	5	5	5	6	7	5	10	16
sd	8	8	7	8	8	11	12	13	15

Air-bone gap results

Unmasked bone conduction testing, using forehead bone oscillator placement was completed during V1 only. Results shown in Table 3 represent the average of the differences between the pure tone thresholds of the best ear and bone conduction thresholds at 500, 1000, and 2000 Hz. Participants who were eligible to take part in the study were analyzed separately from participants who were not eligible to take part in the study. Mean air-bone gaps were 4 dB for both groups, which is consistent with a normal conductive hearing mechanism. The standard deviation and upper limit of the 90% range was higher for those who were not eligible to complete the study, as expected, because the ineligible group included a few individuals with abnormal middle ear results.

Table 3. Average air-bone gap (dB) between pure tone air conduction thresholds in the best ear at 500, 1000, and 2000 Hz and bone conduction thresholds.

	Mean	**SD**	**90% range**	**n**
Participants completing V2	4	4	(-3-12)	190
Participants not eligible for V2	4	6	(-5-15)	79

Tympanometric results

Results of conventional and wideband middle ear assessments indicated normal effective volume, static admittance, peak pressures, and tympanometric widths for the participants completing V2 (Table 4). Mean results among those ineligible to complete V2 were also consistent with normal middle ear function. There were rare cases indicating abnormal peak pressures, but these cases did not appear to affect substantially the measure of tympanometric width, which is a sensitive indicator of middle ear dysfunction.

The resonance frequencies for wideband absorbance at ambient pressure and wideband tympanometry testing have been used to sub-divide the frequency spectrum during analyses of reflexive tasks (see below). The resonance frequency for the wideband absorbance measure was determined as the frequency at the location where the phase of the wideband absorbance function first crosses zero. The mean resonance frequency for the wideband absorbance function was approximately 3500 Hz for eligible and ineligible participants alike (Table 5), and there were a few ineligible participants with atypically low wideband absorbance resonance frequencies. The resonance frequency for the wideband tympanometry test is a quantity returned by the measurement system. The mean wideband tympanogram resonance frequency was around 700 to 760 Hz, with a trend toward lower mean resonance frequencies among ineligible participants (Table 6).

Table 4. Tympanometric results, including ear canal volume, compliance, peak pressure, and tympanometric width, for participants who were eligible to take part in the study and completed V2, and for those who were not eligible to complete the study.

		Mean	SD	90% range	n
Participants completing V2, Left ear					
	Volume (cm^3)	1.24	0.30	(0.83-1.81)	190
	Admittance (mmho)	0.76	0.68	(0.29-1.44)	189
	Peak Pressure (daPa)	-4.17	22.23	(-21.00-10.00)	189
	Tympanic Width (daPa)	79.38	32.56	(30.00-133.00)	189
Participants completing V2, Right ear					
	Volume (cm^3)	1.29	0.31	(0.85-1.86)	190
	Admittance (mmho)	0.70	0.49	(0.27-1.50)	190
	Peak Pressure (daPa)	-5.05	25.74	(-26.00-14.00)	190
	Tympanic Width (daPa)	80.81	34.10	(35.00-126.00)	190
Participants not eligible for V2, Left ear					
	Volume (cm^3)	1.36	0.66	(0.77-2.05)	79
	Admittance (mmho)	0.92	0.72	(0.28-2.77)	77
	Peak Pressure (daPa)	-14.66	38.22	(-88.00-9.00)	77
	Tympanic Width (daPa)	78.57	44.36	(15.00-142.00)	77
Participants not eligible for V2, Right ear					
	Volume (cm^3)	1.49	0.69	(0.80-2.81)	79
	Admittance (mmho)	1.00	0.84	(0.29-3.03)	77
	Peak Pressure (daPa)	-17.58	53.02	(-183.00-20.00)	77
	Tympanic Width (daPa)	75.55	45.16	(18.00-166.00)	77

Table 5. Wideband Absorbance resonance frequency (Hz) results for participants who completed the study and for those who were not eligible to complete the study.

		Mean	SD	90% range	n
	Participants completing V2, left ear	3504	816	(2594-4757)	190
	Participants completing V2, right ear	3499	720	(2448-4757)	190
	Participants not eligible for V2, Left ear	3504	906	(1297-4757)	78
	Participants not eligible for V2, Right ear	3511	954	(1411-4757)	78

Table 6. Wideband Tympanometry resonance frequency (Hz) results for participants who completed the study and for those who were not eligible to complete the study.

		Mean	SD	90% range	n
	Participants completing V2, left ear	743	127	(537-879)	189
	Participants completing V2, right ear	760	123	(548-882)	189
	Participants not eligible for V2, Left ear	711	155	(398-872)	78
	Participants not eligible for V2, Right ear	718	149	(416-1006)	77

Maximum reflex magnitudes

Acoustic reflex results were described in terms of maximum change in effective volume (ml) at the maximum level tested. Results are described by ear, frequency and laterality in Table 8 only for participants who were eligible to take part in the study and completed V2 of the study. Results are comprised of reflex levels only at the maximum level tested between presentation levels 80, 85, 90, 95, and 100 dB HL. The maximum level tested was often, but not always, the point where a .05 ml change in impedance was observed. In cases where the change in impedance was less than .05 ml, the level observed at the maximum presentation level of 100 dB HL was used.

Table 7. Maximum reflex magnitude (change in effective volume, measured in ml), ipsilateral and contralateral for left and right ears, at 500, 1000, 2000, and 4000 Hz.

Ear	Stimulus Frequency	Mean	SD	90% range	N
Ipsilateral					
Left	500	0.09	0.04	(0.04-0.16)	189
	1000	0.09	0.04	(0.04-0.18)	189
	2000	0.09	0.05	(0.01-0.19)	189
	4000	0.08	0.04	(0.02-0.16)	189
Right	500	0.08	0.03	(0.03-0.15)	189
	1000	0.09	0.04	(0.04-0.16)	189
	2000	0.09	0.05	(0.01-0.18)	189
	4000	0.08	0.05	(0.02-0.17)	189
Contralateral					
Left	500	0.06	0.04	(0.01-0.12)	189
	1000	0.06	0.04	(0.01-0.11)	189
	2000	0.07	0.04	(0.00-0.14)	189
	4000	0.06	0.04	(0.01-0.13)	189
Right	500	0.06	0.03	(0.01-0.12)	189
	1000	0.06	0.04	(0.01-0.13)	189
	2000	0.06	0.05	(0.00-0.14)	189
	4000	0.06	0.04	(0.00-0.14)	189

Reflex Detection Methods

McGregor et al (under review) summarized reflex results on 285 participants completing V1. This includes all participants who completed V1, regardless of their eligibility to complete the study. Two methods of reflex detection were developed and implemented using custom written MATLAB scripts. These methods are similar, but not identical to the *Frequentist* and *Bayesian/Kalman* methods described in Flamme et al (2017). The first method, referred to as the conventional method, identifies a reflex as present if the maximum change in impedance is greater than 0.02 ml, based on the underlying assumption that a change of this magnitude would occur only infrequently in the absence of an MEMC. One disadvantage of the conventional method is that the morphology of the reflex is not taken into consideration. The second method, referred to as the correlational method, identifies a reflex as present if the correlation between that trace and one of a set of reflex prototypes exceeds a correlation coefficient "cut-point".

Prototype and Cut-point Determination

All traces collected for each frequency/laterality combination were viewed on the same figure to show reflex growth and morphology patterns. Using MATLAB, exploratory examination and review of the traces identified eleven prototypical shapes that best describe the morphology of the traces. Further analyses of the prototypes determined

that four prototypes were highly correlated to at least one of the remaining prototypes, and could therefore be merged together.

In order to determine correlation cut-point for declaring that an AR was present, 406 reflex traces were selected randomly from the dataset. Four raters (KM, GF, ST, KD) independently viewed each trace and made binary judgments on the presence/absence of a stimulus-linked change in the trace (i.e., an AR). Presence of a reflex was judged only on the morphology of the reflex. The time axis scaling remained so that the judge could confirm that the reflex was time-linked to the elicitor.

Traces in which all four judges agreed that a reflex was present were classified as true reflexes. All other traces, including those where 2 of 4 or 3 of 4 judges agreed, were labeled as no reflex present. The binary indicators for all 406 traces were then used to complete a Receiver Operating Characteristic (ROC) curve, which produced the sensitivity and specificity of this identification method at various cut-points. Sensitivity/specificity was optimized at a correlation cut-point of 0.8617.

Statistical Analysis

Proportions of present AR and 90 % confidence intervals and analyses were calculated using the Stata software package (StataCorp, College Station, TX). The 90 % confidence interval was used because the lower bound of the 90 % confidence interval represents the point above which 95 % of observations would be expected to fall under infinite repeated random sampling of a population.

Proportions of Acoustic Reflexes

The results for the correlational detection method are shown in Table 9. Each ear was analyzed separately, for each elicitor frequency and each laterality. The bilateral category represents the proportion of participants with present AR at the elicitor frequency in both ears. An individual is less likely to have an AR in both ears than in only one, and therefore, the proportions of AR are lower for the bilateral category than for left or right ear separately. Each category also includes "1 or 2 kHz" in the ipsilateral condition for comparison with results from the NHANES study (Flamme et al, 2017), analyzed using the same criteria. We have calculated the proportion of participants with a reflex present at either 1 or 2 kHz for the left ear, right ear, and in both ears for the ipsilateral condition only. This proportion will be higher than either 1 or 2 kHz on its own. Similar results for the conventional detection method are shown in Table 10.

As discussed previously, an AR is considered pervasive when the lower bounds of the 90% confidence interval exceed 0.95. We were unable to find a category, using either detection method, that met this criterion. It is, however, important to notice two trends in these results. First, the proportion of AR was lower for the contralateral AR than for the ipsilateral AR at every elicitor frequency. This trend was found with both detection methods. The difference (as a percentage) between ipsilateral and contralateral AR ranges from 6.7% to 20.4% (mean: 11.9%, SD: 3.87%).

Another important trend in these results is that the proportions of AR at 0.5 and 1 kHz were higher than those at 2 and 4 kHz. To quantify this difference, we found the average of the proportions at 0.5 and 1 kHz (referred to as 0.5-1 average) and at 2 and 4 kHz (2-4 average) for each condition. The 2-4 average was subtracted from the 0.5-1 average to calculate the difference (presented as a percentage). The mean differences were as follows: 4.3% (SD:0.43%) for ipsilateral, correlational method; 5.55% (SD:1.90%) for contralateral, correlational method; 8.28% (SD:1.81%) for ipsilateral, conventional method; 2.55% (SD:0.17%) for contralateral, conventional method.

Table 8. Proportions of acoustic reflexes determined using the correlational detection method.

	Ipsilateral			Contralateral		
		90% confidence limits			*90% confidence limits*	
Stimulus Frequency	*Proportion*	*Low*	*High*	*Proportion*	*Low*	*High*
Left Ear						
500 Hz	0.92	0.89	0.94	0.83	0.79	0.87
1000 Hz	0.94	0.91	0.96	0.86	0.82	0.89
2000 Hz	0.89	0.85	0.92	0.79	0.75	0.83
4000 Hz	0.90	0.86	0.92	0.75	0.71	0.79
1 or 2 kHz	0.96	0.94	0.98	–	–	–
Right Ear						
500 Hz	0.92	0.88	0.94	0.85	0.81	0.88
1000 Hz	0.93	0.90	0.95	0.82	0.78	0.86
2000 Hz	0.88	0.85	0.91	0.80	0.76	0.84
4000 Hz	0.87	0.84	0.90	0.80	0.75	0.83
1 or 2 kHz	0.94	0.91	0.96	–	–	–
Bilateral						
500 Hz	0.86	0.83	0.89	0.76	0.72	0.80
1000 Hz	0.89	0.85	0.92	0.76	0.72	0.80
2000 Hz	0.83	0.79	0.87	0.72	0.67	0.76
4000 Hz	0.83	0.79	0.86	0.69	0.64	0.73
1 or 2 kHz	0.92	0.89	0.94	–	–	–

Table 9. Proportions of acoustic reflexes determined using the conventional (0.02 ml impedance change) method.

	Ipsilateral			Contralateral		
		90% confidence limits			*90% confidence limits*	
Stimulus Frequency	*Proportion*	*Low*	*High*	*Proportion*	*Low*	*High*
Left Ear						
500 Hz	0.96	0.93	0.97	0.80	0.76	0.84
1000 Hz	0.95	0.93	0.97	0.81	0.77	0.84
2000 Hz	0.87	0.83	0.90	0.79	0.74	0.82
4000 Hz	0.87	0.84	0.90	0.77	0.73	0.81
1 or 2 kHz	0.97	0.94	0.98	–	–	–
Right Ear						
500 Hz	0.94	0.92	0.96	0.81	0.77	0.85
1000 Hz	0.94	0.92	0.96	0.79	0.74	0.82
2000 Hz	0.88	0.85	0.91	0.78	0.74	0.82
4000 Hz	0.88	0.84	0.91	0.77	0.73	0.81
1 or 2 kHz	0.95	0.93	0.97	–	–	–
Bilateral						
500 Hz	0.92	0.89	0.94	0.72	0.67	0.76
1000 Hz	0.91	0.88	0.93	0.71	0.66	0.75
2000 Hz	0.81	0.77	0.85	0.69	0.64	0.73
4000 Hz	0.82	0.78	0.85	0.68	0.63	0.73
1 or 2 kHz	0.93	0.90	0.95	–	–	–

Evaluation of RTs

Analyses of reflexive tasks have been conducted based on comparisons of the RMS difference in the filtered pressure waveform developed in the ear canal for clicks during the elicitor interval relative to the mean pressure waveform during the baseline interval, which immediately preceded the elicitor interval. The 25th percentile of the RMS differences as a function of time within the elicitor interval were then examined visually for an increase in the RMS difference coinciding with the elicitor stimulus. The impedance change caused by a reflexive MEMC presents as a consistent change in the RMS difference that coincides with the elicitor stimulus.

Plots of the 25th percentiles of the RMS differences were examined visually by three raters for evidence of reflexive MEMC in 120 study participants to date. The proportions of cases in which all raters identified a reflexive MEMC and at least one rater identified a reflexive MEMC are presented for each acoustic stimulus and sub-type of non-acoustic stimulus in Figure 3. The results of these analyses indicated that the non-acoustic elicitors were more likely to produce a stimulus-linked change in RMS differences, and that only one of the stimuli approached the status of eliciting a pervasive MEMC. This stimulus was an instruction to close the eyelid ipsilateral to the probe at maximal effort. Among the acoustic elicitors, the white noise and 1 kHz stimuli were the most likely to elicit a reflexive MEMC.

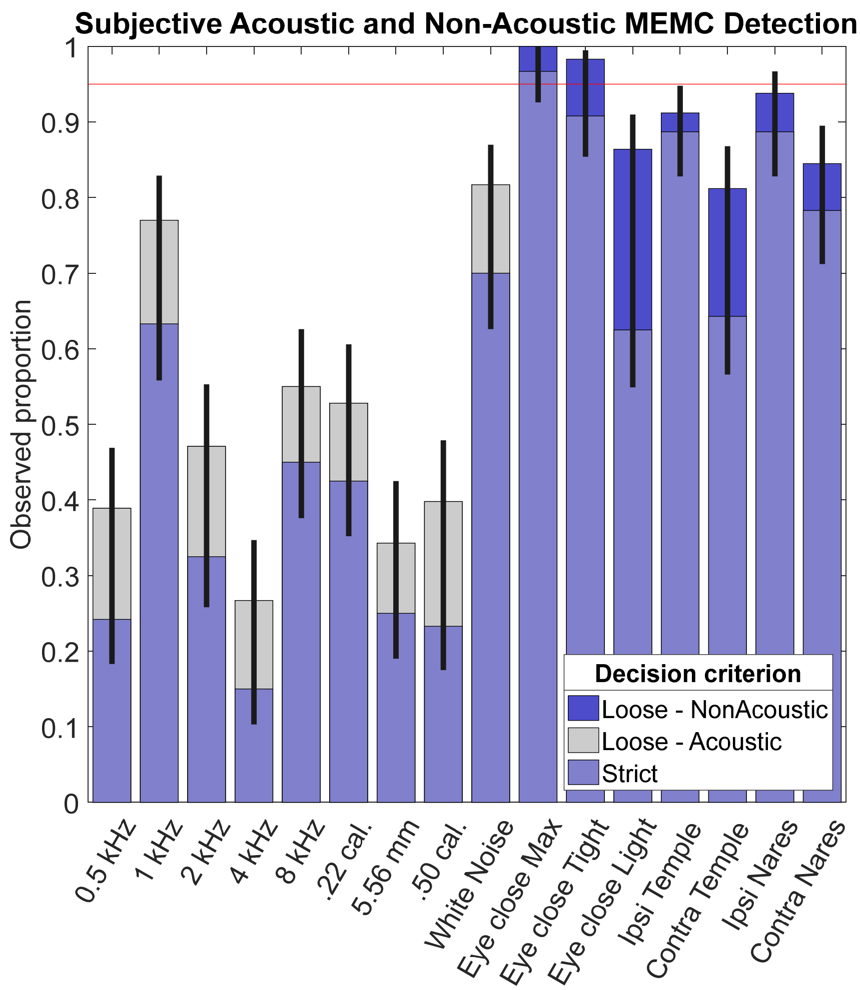


Figure 3. Proportions of MEMC by visual detection across 3 raters for 120 participants. The proportion represented by the Loose criterion represents MEMC detected by at least one rater. The proportion represented by the Strict criterion represents MEMC detected by all raters. Error bars encompass the range from the lower bound of the 90 % confidence interval for the strict criterion to the upper bound of the 90 % confidence interval for the loose criterion. The white noise and 1000 Hz tone were the most effective elicitors for the white noise stimulus. A greater proportion of the sample exhibited non-acoustic reflexive MEMC tasks than acoustic reflexive MEMC, particularly for the maximum and tight eye close tasks and the air puff stimuli delivered ipsilateral to the probe ear.

The RMS-based approach to reflex assessment described above includes the entire frequency spectrum of the click used as a probe signal (i.e., 200 – 8000 Hz). Therefore, any detected RMS change from the baseline signal is lumped across the probe signal bandwidth. Some of these changes could include variations in physiological noise and other acoustic events that are unlikely to represent MEMC. It is plausible that the detection of MEMC could be improved by calculating differences in the complex Fast Fourier Transform (FFT) and subdividing the broadband response into narrow-band frequency regions.

This so-called "FFT-based" approach allows greater control to be exerted over the frequency ranges contributing to the evaluation, and this makes it possible to base MEMC detection judgements on individual characteristics of the participant's ears (e.g., resonance frequencies). Furthermore, a method based on the FFT permits evaluations of multiple aspects of changes in the FFT (e.g., real magnitude, phase, and the change in the complex magnitude of the FFT). The RMS-based approach is sensitive only to changes from the baseline response. It is not sensitive to whether the change is in the positive direction (i.e., more reflection of the middle ear system), negative direction (more absorbance in the middle ear system), or a mixed effect that varies with frequency. We are exploring methods for extracting these details from the FFT-based analyses.

In addition to developing FFT-based summaries of the data, we have also re-examined how changes in the ear during the elicitor period are represented. As noted above, the conventional strategy was to examine the RMS of the differences in the pressure waveform for each time frame in the elicitor interval (i.e., the response to each 50 ms click window) against the baseline pressure waveform. For example, the RMS value at time = 0.60 s relative to elicitor onset would represent the difference from baseline during that click interval. It seemed plausible that a clearer indication of the MEMC could be obtained by examining changes in differences from the baseline click, which can be accomplished by stepping through the click interval and subtracting the prior value from the current value to determine the change.

An example of the results returned by the FFT-based strategy is represented in Figure 4. The panels in this figure show the changes in the FFT modulus as a function of frequency for each elicitor trial while also providing representations of the reflexive MEMC in multiple frequency bands.

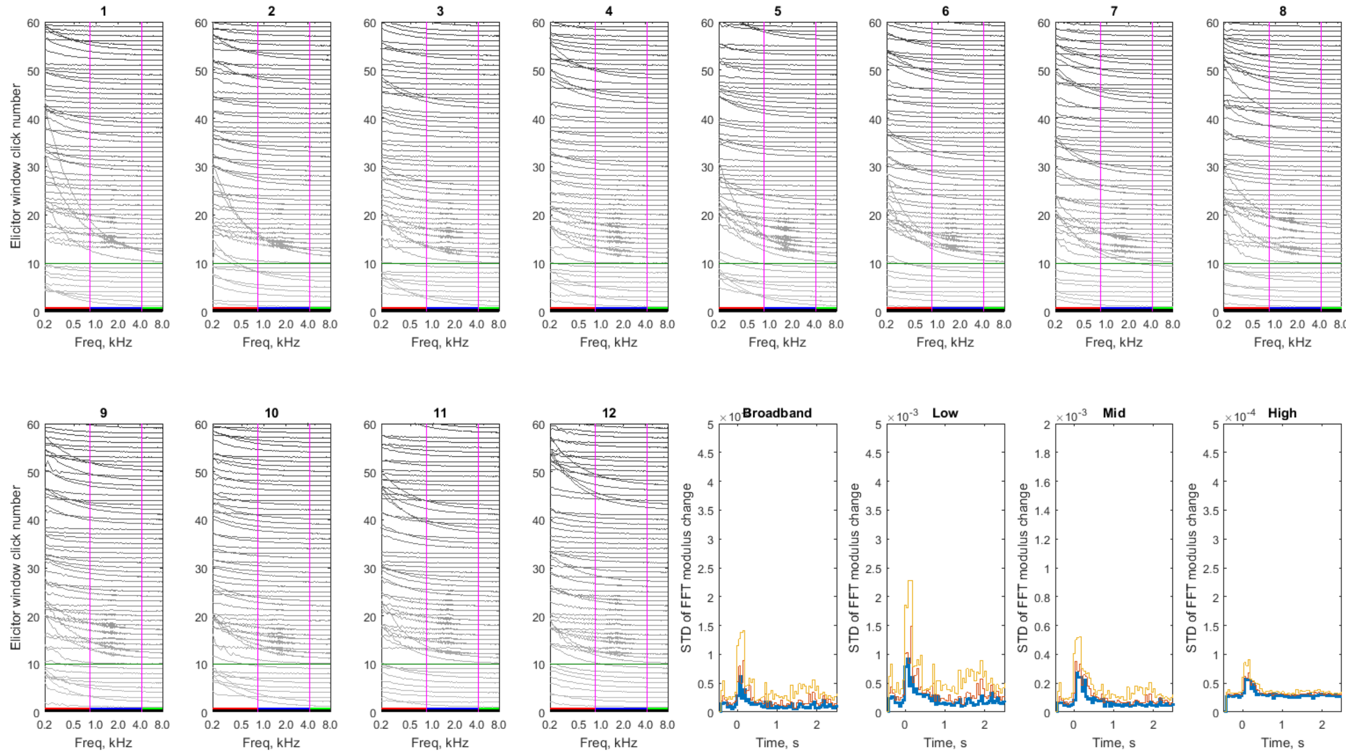


Figure 4. Summary example of reflexive task results for a single stimulus and a single participant. Waterfall plots (i.e., the first row and the first four columns of the second row) represent results from individual elicitor presentations. The final four columns in the second row represent the broadband and band-limited FFT differences across the elicitor window. The horizontal axis of the waterfall plots represents frequency. The vertical axis represents the difference in the modulus of the FFT band, which is shifted upward for each click number during the elicitor window. The interval between clicks was 50 ms. The onset of the elicitor is indicated by the green horizontal line. The resonance frequency of the participant's middle ear, as measured using wideband tympanometry, is represented by the left magenta line. The resonance frequency of the ear at ambient pressure, as measured by the zero-crossing of the phase of the wideband absorbance function, is represented by the right magenta line. The plots of FFT differences over time represent time in seconds on the horizontal axis and the RMS of the change in the FFT modulus on the vertical axis. Parameters are the 25^{th}, 50^{th}, and 75^{th} percentiles of the change in the FFT difference. The 25^{th} percentile is the main quantity of interest and is represented in bold. The broadband plot represents responses at the frequencies between 200 and 8000 Hz. The low-frequency plot represents responses at the frequencies between 200 Hz and the resonance frequency of the participant's middle ear. The mid-frequency plot represents responses at the frequencies between the middle ear resonance and the resonance of the ear at ambient pressure. The high-frequency plot represents the responses at the frequencies between the resonance of the ear at ambient pressure and 8000 Hz.

We have observed that the time courses of the changes are occasionally inconsistent across frequency bands. In some cases, elicitor-linked changes in the high-frequency band can initiate before the mid- and low-frequency bands (see Figure 5), and it is not uncommon that the peak differences occur at different times in differing frequency bands. Furthermore, the most prominent differences are frequently observed in frequency ranges that are not the most affected by MEMC. The reasons for frequency-specific differences in response are unclear, but these results suggest that the elicitor-linked changes could be derived from multiple mechanisms.

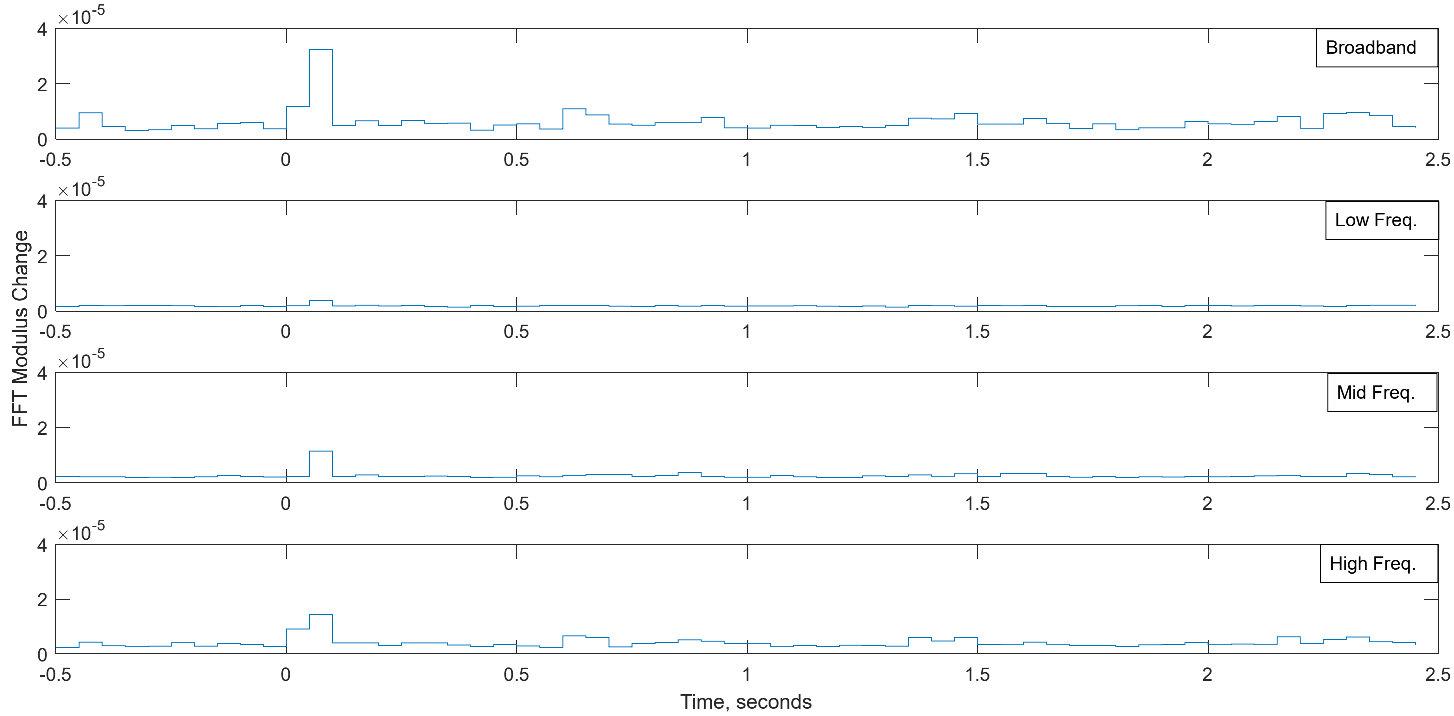


Figure 5. Example of MEMC response across frequency bands. Broadband response includes frequencies between 200 and 8000 Hz. Low frequency includes frequencies between 200 Hz and the resonance frequency of the middle ear as measured using wideband tympanometry. Mid frequency includes frequencies between the resonance frequency of the middle ear and the resonance frequency of the ear as measured using wideband absorbance at ambient pressure. High frequency incudes frequencies between the resonance frequency of the ear and 8000 Hz. The horizontal axis in each plot represents time in seconds relative to the onset of a white noise elicitor signal. The vertical axis represents the mean of the FFT modulus change within the indicated frequency band. The time course of the stimulus-linked disturbance in the FFT modulus varies with frequency, suggesting more than one underlying mechanism.

Group-level evaluations of reflexive MEMC

This study was designed to assess whether there was 95 % confidence that the prevalence of MEMC was at or above 95 % for a variety of reflexive and conditioned tasks. A binary decision about the presence or absence of MEMC can inform decisions about whether it is justified to include MEMC in DRC for impulsive noise. However, the current study can also provide some information about how a role for MEMC should be implemented if such a decision were made. If included, the MEMC would be expected to be present at or above a specific magnitude for all (or nearly all) exposures falling within the scope of the DRC. This requirement suggests that it would be most protective to presume a magnitude of MEMC that is at the lower end of the distribution of observed effects. We are in the process of developing group-level estimates of MEMC magnitude that can inform these estimates (see Figures 6 through 8). This interim evaluation indicates a very small MEMC response magnitude for the 5th percentile participant on the acoustic elicitors (Figure 6). The response for the 5th percentile participant exceeds the 95 % confidence interval of the trace baseline only slightly and only for the 1000 Hz and white noise elicitors. These results are consistent with the binary findings presented above (see Figure 3), which showed that these elicitors were most likely to produce an MEMC.

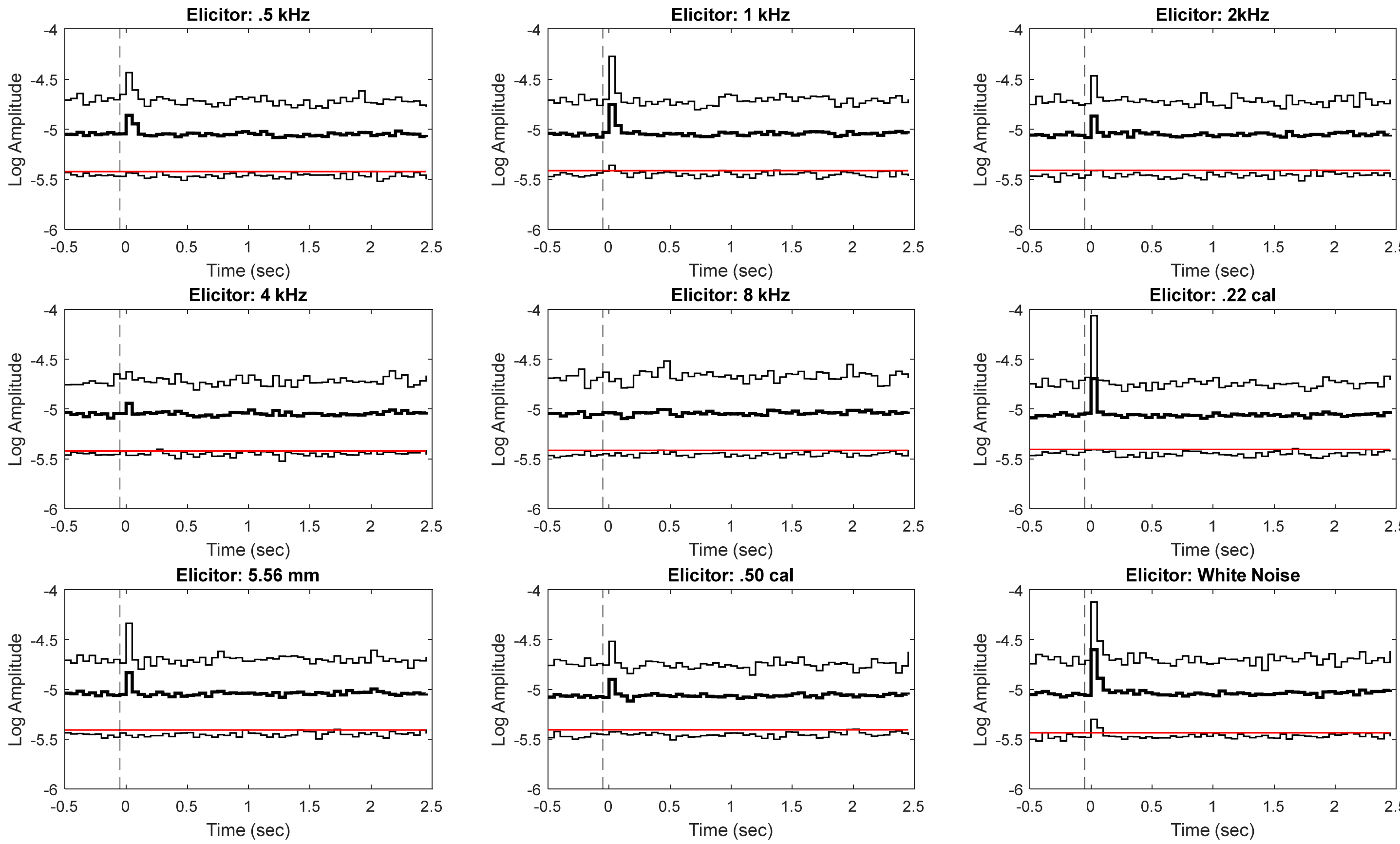


Figure 6. Summary of acoustic reflexive task results for 106 participants. Each plot represents an acoustic elicitor condition. The horizontal axis of each plot represents time relative to the onset of the elicitor. The vertical axis represents the logarithm of the RMS difference of the modulus of an FFT band (200-8000 Hz). Within each panel, the bold line represents the mean of the 25th percentile trace generated for each of the 106 participants (see Figure 3). The lower and upper light black lines respectively represent the 5th and 95th percentile of the distribution for participant group. The horizontal red line represents the 95th percentile of the distribution of the 5th percentile baseline, defined as the final 20 samples (1 second) of the analysis window.

In contrast, the 95 % confidence interval for the trace baseline was exceeded in all the effort levels in the eye close task (Figure 7) and for all stimulus locations on the air puff task (Figure 8). In the eye close tasks, the MEMC response appears to last the entire duration of the eye close gesture (3 seconds). In the air puff task, the magnitude of the MEMC was greater for the ipsilateral stimulus locations than the contralateral locations, which is consistent with the binary findings presented above (see Figure 3).

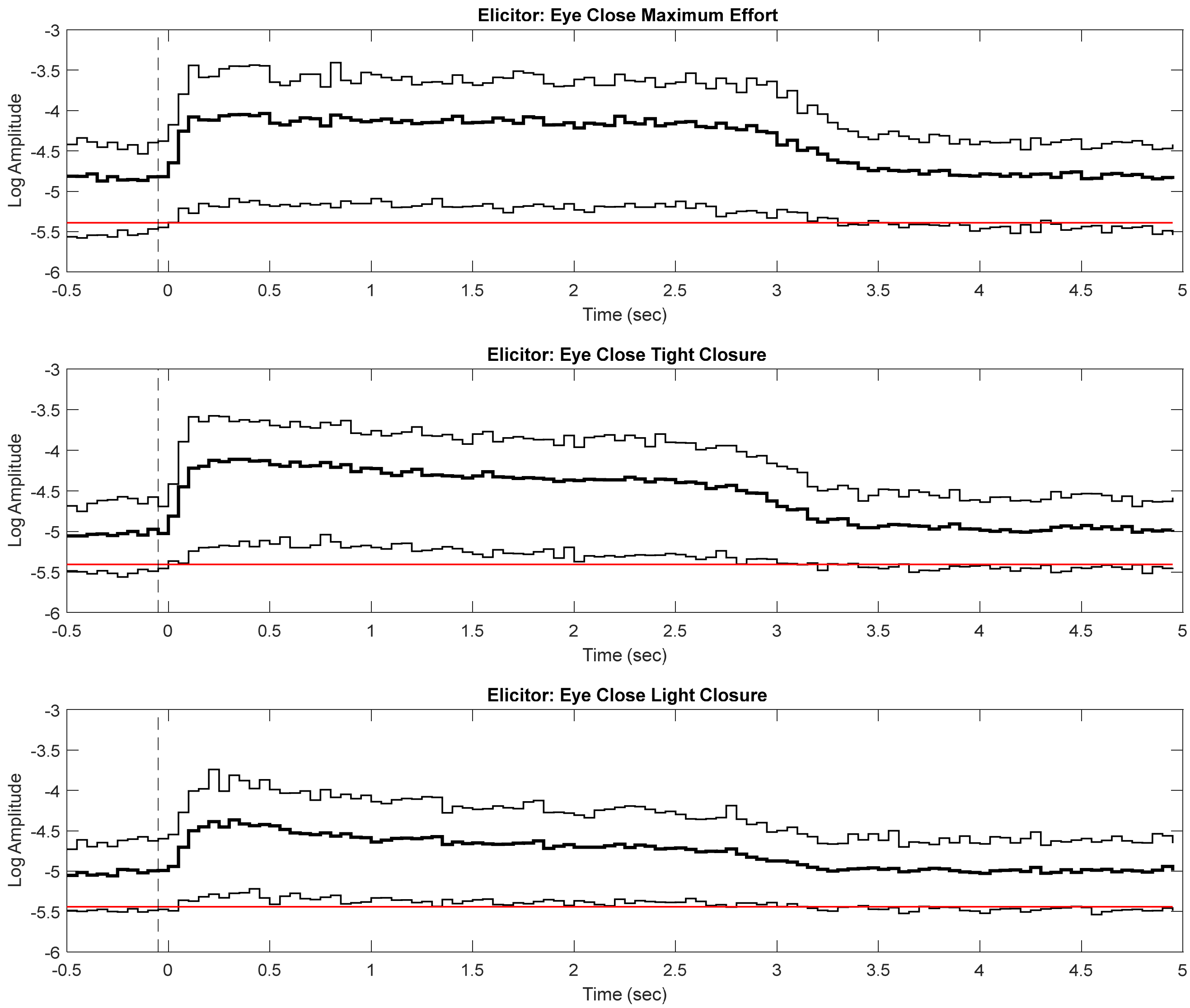


Figure 7. Summary of eye close task for 106 participants. The top plot represents the maximum effort eye close condition. The middle plot represents the tight closure condition and the bottom plot represents the light closure condition. The horizontal axis of each plot represents time relative to the onset of the elicitor. The vertical axis represents the logarithm of the RMS difference of the modulus of an FFT band (200-8000 Hz). Within each panel, the bold line represents the mean of the 25th percentile trace generated for each of the 106 participants (see Figure 3). The lower and upper light black lines respectively represent the 5th and 95th percentile of the distribution for participant group. The horizontal red line represents the 95th percentile of the distribution of the 5th percentile baseline, defined as the final 20 samples (1 second) of the analysis window.

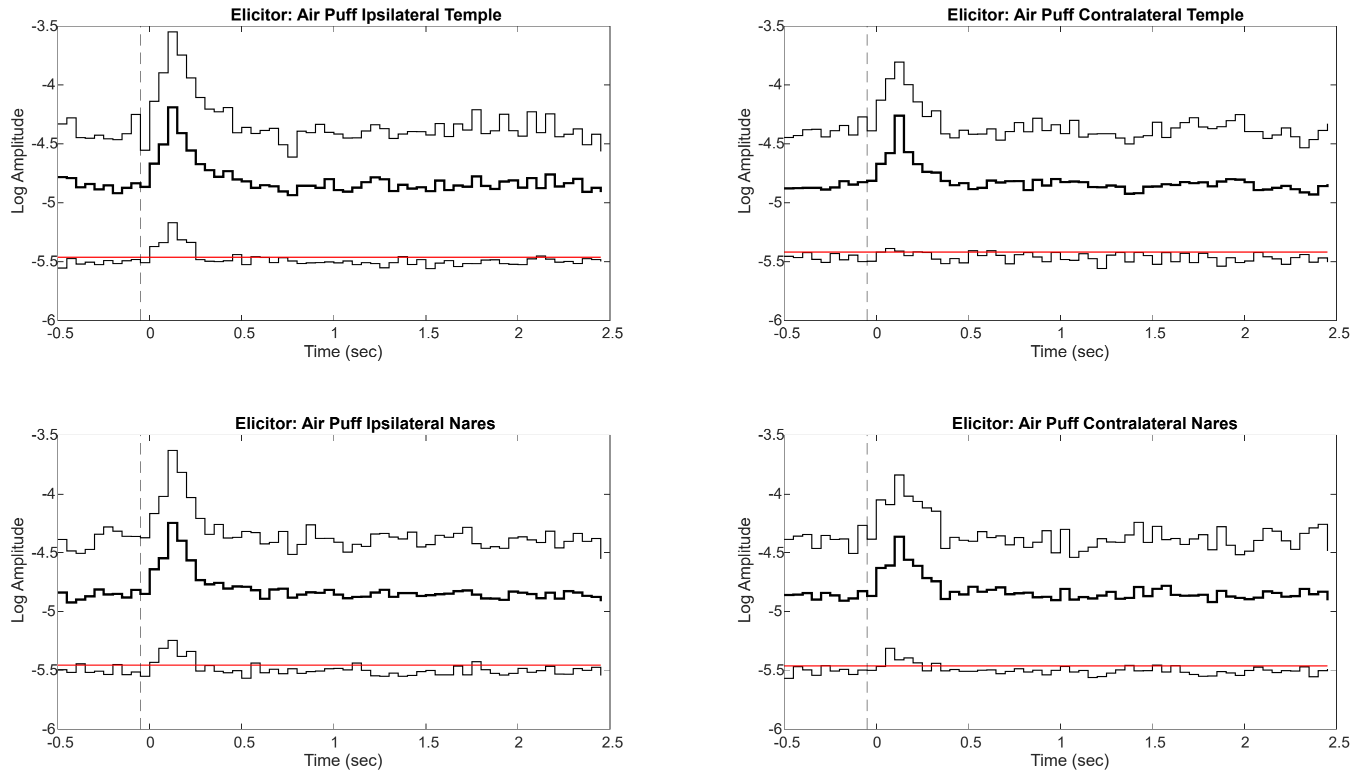


Figure 8. Summary of air puff reflexive task for 106 participants. Puffs of air were randomly presented to four possible locations on the face. The top left and right plots represent the temple location ipsilateral and contralateral to the probe ear. The bottom left and right plots represent the nares location ipsilateral and contralateral to the probe ear. The horizontal axis of each plot represents time relative to the onset of the elicitor. The vertical axis represents the logarithm of the RMS difference of the modulus of an FFT band (200-8000 Hz). Within each panel, the bold line represents the mean of the 25th percentile trace generated for each of the 106 participants (see Figure 3). The lower and upper light black lines respectively represent the 5th and 95th percentile of the distribution for participant group. The horizontal red line represents the 95th percentile of the distribution of the 5th percentile baseline, defined as the final 20 samples (1 second) of the analysis window.

Evaluation of Conditioned Tasks

The raw data for the conditioned tasks were similar to those obtained for the reflexive tasks, which permits the processing and detection algorithms to be applied to both types of task with only minor modification. To date, we have focused primarily on optimizing the routines for the reflexive tasks, but have recently begun processing the conditioned tasks using the optimized routines. Examples of results from the Attended Auditory, Unattended Auditory, and Attended Light tasks are represented in Figure 9 . These traces in these plots represent the 25th percentile of the responses to trials that pair the unconditioned and conditioned stimuli. Since the conditioned stimulus leads the unconditioned stimulus (acoustic elicitor), an MEMC that begins before the elicitor would suggest some conditioning has occurred. The upper left plot is an example of such a shift. Note there is a rise from the baseline well before the elicitor onset (0 sec). Our preliminary examinations of these data suggest that, while evidence of conditioning has been observed, it does not appear to be pervasive and varies with the sensory modality used for the conditioning stimulus and whether the participant's attention is drawn from the auditory stimuli.

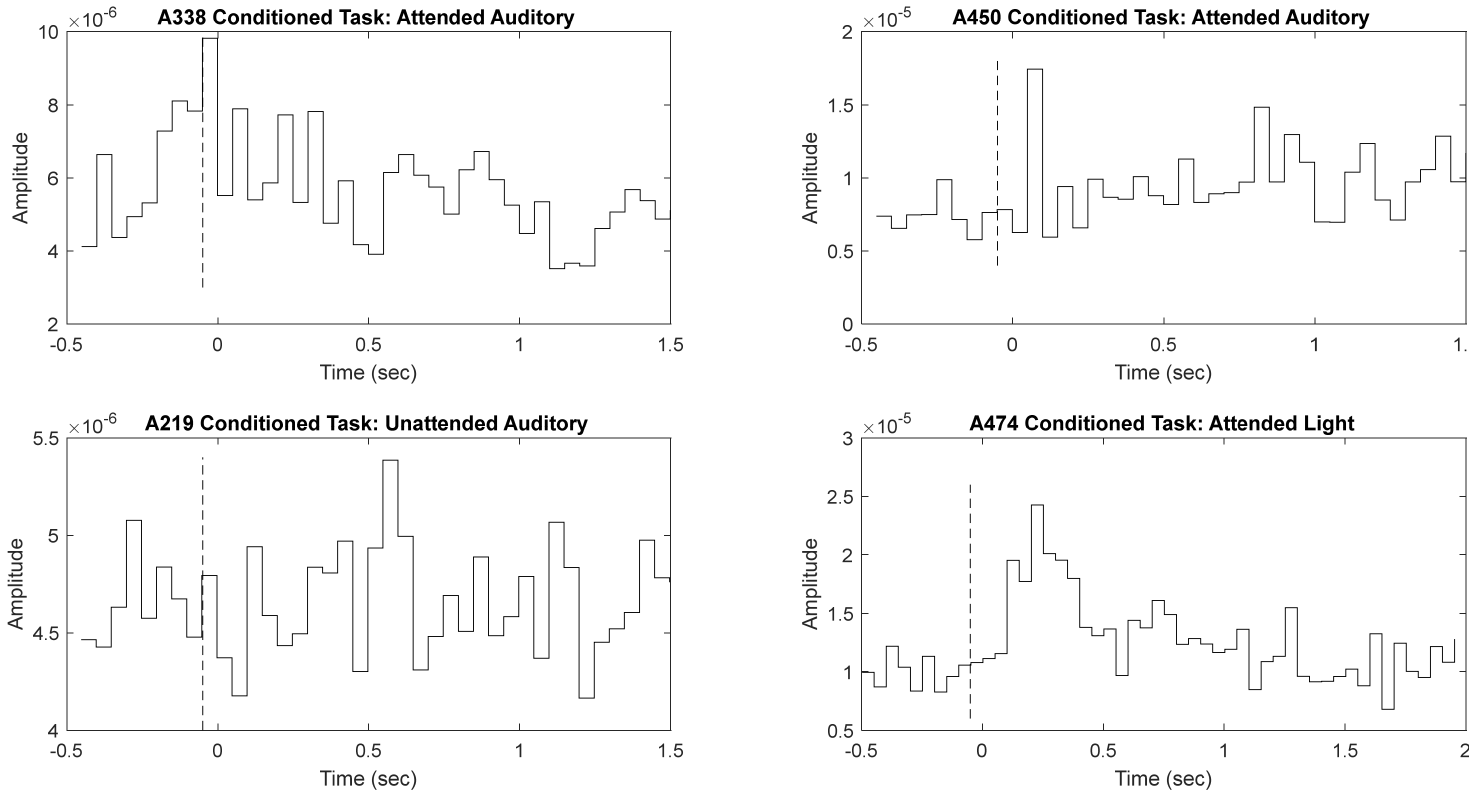


Figure 9. Example results from the Attended Auditory, Unattended Auditory, and Attended Light conditioned tasks. The horizontal axis represents time, with time=0 representing the onset of the unconditioned stimulus (i.e., a white noise). The vertical axis represents the difference in RMS difference of the modulus of an FFT band (200-8000 Hz). Each trace represents the 25th percentile of the responses associated with trials that paired the unconditioned and conditioned stimuli. Evidence of conditioning would be a -A conditioned MEMC seems likely for the Attended Auditory task for participant A338 (upper left panel), as illustrated by the increase in amplitude prior to time=0. However, a conditioned MEMC is unlikely in any of the other examples. The two right panels show possible reflexive MEMC to the white noise unconditioned stimulus, but there is no clear reflexive MEMC for the unattended auditory example in the lower left corner.

What opportunities for training and professional development has the project provided?
Nothing to report.

How were the results disseminated to communities of interest?

Presentations were made at: the 5th joint meeting of the Acoustical Society of America; the 40th Annual Association for Research in Otolaryngology; the National Hearing Conservation Association Meeting; the second Japan-US Forum on Blast Injury 2017 (JUFBI-2017); the 88th Annual Scientific Meeting of the Aerospace Medical Association; and the 2017 Military Health Science and Research Symposium.

What do you plan to do during the next reporting period to accomplish the goals?

During the next reporting period, our efforts will focus on completing the data collection at USAARL and publishing manuscripts summarizing our results on laboratory reflexive and conditioned stimulus MEMC data collection.

Impact

What was the impact on the development of the principal discipline(s) of the project?

In the field of hearing science, the methods developed for this study enable the assessment of MEMC for a wide range of stimuli, and ultimately this project will inform the development of damage-risk criteria for impulsive noises.

To date, the results of this work suggest that clinical reflexive MEMC are not pervasive in the U.S. population and that people with clinical reflexive MEMC do not necessarily exhibit MEMC for brief tones, noises, or recorded gunshots. Non-acoustic elicitors appear more likely to produce an MEMC than acoustic elicitors. In addition, the refined methods for detecting MEMC that were developed for this study provide a means for future studies of these phenomena.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

The MEMC has been assumed to have a protective role in multiple damage-risk criteria for impulsive sounds. Some damage-risk criteria have presumed that a listener who knows of an imminent impulse will produce anticipatory protective MEMC via classical conditioning. There is a weak evidentiary basis for a protective role of MEMC for such brief sounds, and the evidentiary basis for an anticipatory MEMC is nearly non-existent. The current project is likely to inform the development and application of damage-risk criteria and health hazard evaluations by policymakers. The consequent improvements in the accuracy of damage risk criteria will benefit warfighters and other personnel exposed to impulsive sounds in the line of their duty and occupation. In addition, these criteria could inform the evaluation of the hazard of impulsive noise for firearm users.

Changes/Problems

Changes in approach and reasons for change

The conventional analysis based on RMS differences has been modified for frequency limited/specific differences to examine the possibility that the stimulus-linked response may differ across frequency. There is a reasonable likelihood that this change will facilitate algorithm-based identification of MEMC.

Actual or anticipated problems or delays and actions or plans to resolve them

Dr. Greene's departure from USAARL has engendered a modification of the roles assigned to USAARL personnel and SASRAC. We plan to shift some duties to the SASRAC team to focus the efforts at USAARL on completing data collection at that site. We also plan to request a one-year no-cost extension of the project.

Changes that had a significant impact on expenditures

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Field study IRB amendment has been classified as a greater than minimal risk study and will be conducted with the human subject protections consistent with that classification.

PRODUCTS:

Publications, conference papers, and presentations

Journal publications.

McGregor, KD, Flamme GA, Tasko SM, Deiters, KK, Ahroon, WA, Themann, CL, Murphy WJ (under review). Acoustic Reflexes are Common but Not Pervasive: Evidence Using a Diagnostic Middle Ear Analyzer. *International Journal of Audiology*.

Flamme GA, Deiters KK, Tasko SM, Ahroon WA (2017). Acoustic reflexes are common but not pervasive: Evidence from the National Health and Nutrition Examination Survey, 1999-2012. *International Journal of Audiology, 56(Supplement 1)*, 52-62.

Conference papers, and presentations

1. Greene NT, Jones HG, Flamme GA, Tasko S, Deiters K, and Ahroon WA. Acoustic and non-acoustic elicitors of middle ear muscle contractions in military and civilian populations. 2017 Military Health Science and Research Symposium (Oral presentation). Kissimmee FL, Aug. 27-30, 2017.

2. Jones HG, Greene NT, and Ahroon WA. Preliminary results: Classical conditioning of the MEMC during the acoustic reflex. 2017 Military Health Science and Research Symposium (Poster presentation). Kissimmee FL, Aug. 27-30, 2017.

3. Jones HG, Greene NT, Ahroon WA. Experimental testing whether the acoustic reflex can be warned. CAVRN (Poster presentation). San Antonio, TX, June 12-15, 2017.

4. Greene NT, Jones HG, Ahroon WA. Assessment of MIL-STD 1474E, the AHAAH model. The Aerospace Medical Association's 88th Annual Scientific Meeting (Oral Presentation). Denver, CO, Apr. 30-May 4, 2017.

5. Jones HG, Greene NT, Hollonbeck SA. Promoting Active Hearing Protection Combined with Communication Capabilities to Improve Situational Awareness and Safety on the Airfield. The Aerospace Medical Association's 88th Annual Scientific Meeting (Oral Presentation). Denver, CO, Apr. 30-May 4, 2017.

6. Flamme GA, Tasko SM, Deiters KK, Greene NT, Ahroon WA. Reflexive and anticipatory middle ear muscle contractions for impulsive sounds. The Aerospace Medical Association's 88th Annual Scientific Meeting (Oral Presentation). Denver, CO, Apr. 30-May 4, 2017.

7. Greene NT, Jones HG, Flamme GA, Ahroon WA. Recent Experiments Assessing Components of the Auditory Hazard Assessment Algorithm for Humans (AHAAH). The 2nd Japan-US Technical Information Exchange Forum on Blast Injury (JUFBI 2017; Invited Presentation). Tokyo, Japan, April 14-16, 2017.

8. Jones HG, Greene NT, Ahroon WA. Warning the acoustic reflex to protect against blast-related auditory injury: Attempt to classically condition the middle ear muscle contraction. The 2nd Japan-US Technical Information Exchange Forum on Blast Injury (JUFBI 2017; Invited Presentation). Tokyo, Japan, April 14-16, 2017.

9. Greene NT, Jones HG, Hollonbeck SA, Ahroon WA. Modelling the Effects of Middle Ear Muscle Contraction on Tympanic Membrane Motion. The Fortieth Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology (ARO; Oral Presentation). Vol 40. Baltimore, MD, Feb. 11-15, 2017.

10. Jones HG, Greene NT, Karch S, Hollonbeck SA, Ahroon WA. Middle Ear Responses Measured at the Tympanic Membrane during the Acoustic Reflex: A Comparison to Clinical Impedance Measures. The Fortieth Annual Mid-Winter Research Meeting of the Association for Research in Otolaryngology (ARO; poster presentation). Vol 40. Baltimore, MD, Feb. 11-15, 2017.

11. Jones HG, Greene NT, Fasanya BK, Hollonbeck SA, Ahroon WA. Assessment of the Middle-ear Assumption of the Auditory Hazard Assessment Algorithm for Humans. The 5th joint meeting of the Acoustical Society of America and the Acoustical Society of Japan, Honolulu HI, November 28-December 2, 2016.

12. Smith MV, Tasko SM, Flamme GA, Deiters KK (2017) Identification of Masseter Muscle Activity during Chewing through an Automated Algorithm. Mid-East Honors Association Annual Conference, Ypsilanti, MI.

13. Tasko SM, Flamme GA, Deiters KK, Ahroon, WA, Murphy WJ (2017) Effects of non-acoustic stimuli on middle ear muscle contractions. National Hearing Conservation Association, San Antonio TX.

14. McGregor KD, Flamme, GA, Tasko SM, Deiters, KK (2017) Pervasiveness of acoustic reflexes among people tested using a diagnostic middle ear analyzer. National Hearing Conservation Association, San Antonio TX.

15. Flamme GA, Mork, H, Tasko SM, Deiters KK, (2017) Detection of Atypical Differences in Wideband Tympanometry. Meeting of the American Auditory Society, Scottsdale, AZ.

16. Flamme GA, Tasko SM, Deiters KK, Ahroon, WA, Murphy WJ (2016) Middle ear muscle contractions from non-acoustic elicitors. 172nd Meeting of the Acoustical Society of America, Honolulu, HI.

17. Tasko SM, Flamme GA, Deiters KK, Smith, MV, Murphy WJ, Jones HG, Greene NT, Ahroon WA (2018) Concomitant head/neck muscle activity and middle ear muscle contractions. National Hearing Conservation Association, Orlando FL.

18. Deiters KK, Flamme GA, Tasko SM, Murphy WJ, Greene NT, Jones HG, Ahroon WA (2018) Generalizability of clinically-measured acoustic reflexes to brief sounds. National Hearing Conservation Association, Orlando FL.

19. Flamme GA, Tasko SM, Deiters KK, Greene NT, Murphy WJ, Jones HG, Ahroon WA (2018) Laboratory Conditioning of Middle Ear Muscle Contractions. National Hearing Conservation Association, Orlando FL.

20. Smith, MV, Tasko SM, Flamme GA, Deiters KK, Murphy WJ, Jones HG, Greene NT, Ahroon WA (2018) Middle ear muscle activity associated with mastication. National Hearing Conservation Association, Orlando FL.

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers, and presentations.

Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

Website(s) or other Internet site(s)

Nothing to report.

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report.

Participants & Other Collaborating Organizations

What individuals have worked on the project?

Name:	William A. Ahroon, Ph.D.
Project Role:	Principal Investigator (USAARL)
Nearest person month worked:	3 (Calendar)
Contribution to Project:	Dr. Ahroon is a Research Psychologist in the Acoustics Branch of the U.S. Army Aeromedical Research Laboratory (USAARL). As the PI for this project, he will be responsible for scientific and programmatic oversight of the project. Specifically, he will guide the protocol through the IRB and other regulatory reviews in implementing the protocol at USAARL, train and supervise research personnel, and facilitate team meetings.

Name:	Nathaniel T. Greene, Ph.D.
Project Role:	Co-Investigator (USAARL)
Nearest person month worked:	5 (Calendar)
Contribution to Project:	Dr. Greene is a Biomedical Engineer employed by the Geneva Foundation, working under the supervision of Dr. Ahroon in the Acoustics Branch of the U.S. Army Aeromedical Research Laboratory (USAARL). Dr. Greene's duties are to develop, test, collect data, and prepare analytic routines for the USAARL portions of this study.

Name:	Gregory A. Flamme, Ph.D.
Project Role:	Principal Investigator (Western Michigan University/SASRAC)
Nearest person month worked:	0.125 (Academic) 0.67 (Summer)

Contribution to Project:	During year 1, Dr. Flamme's duties are to direct the analyses for the reflexive MEMC study, develop, test, and obtain pilot data for the reflexive and lab-based studies of reflexive and conditioned MEMC. During years 2 through 4, he will work on dissemination of prior results, direct the conduct of the lab-based MEMC studies, and coordinate with USAARL to obtain field study data that are maximally comparable across sites.
Name:	Stephen M. Tasko, Ph.D.
Project Role:	Co-Investigator (Western Michigan University/SASRAC)
Nearest person month worked:	0.125 (Academic) 0.67 (Summer)
Contribution to Project:	During year 1, Dr. Tasko's duties are to develop, test, obtain pilot data, and prepare analytic routines for the EMG-based measurements obtained in this study. During years 2 and 3, he will manage the EMG-based measurements, perform ongoing quality assurance tasks, and conduct analyses on these data. During year 4, he will conduct analyses on the WMU EMG measures and work on dissemination of study data.
Name:	Kristy K. Deiters, Au.D.
Project Role:	Co-Investigator (Western Michigan University/SASRAC)
Nearest person month worked:	2.4 (Calendar)
Contribution to Project:	Dr. Deiters will be the project coordinator during all years of the project, focusing on participant recruitment, day-to-day operations, and coordinating efforts between WMU and USAARL. During years 2 through 4, she will also be responsible for data management, quality assurance, descriptive analyses, preparing data sets for inferential analyses, and dissemination.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Dr. Greene has accepted employment at the University of Colorado, effective in early October 2017.

What other organizations were involved as partners?

Nothing to report.

Special Reporting Requirements

Quad Chart:

Attached

Appendices

None

“Effects of Acoustic Impulses on the Middle Ear”

Log Number: 13063028

Award Number: W81XWH-14-2-0140

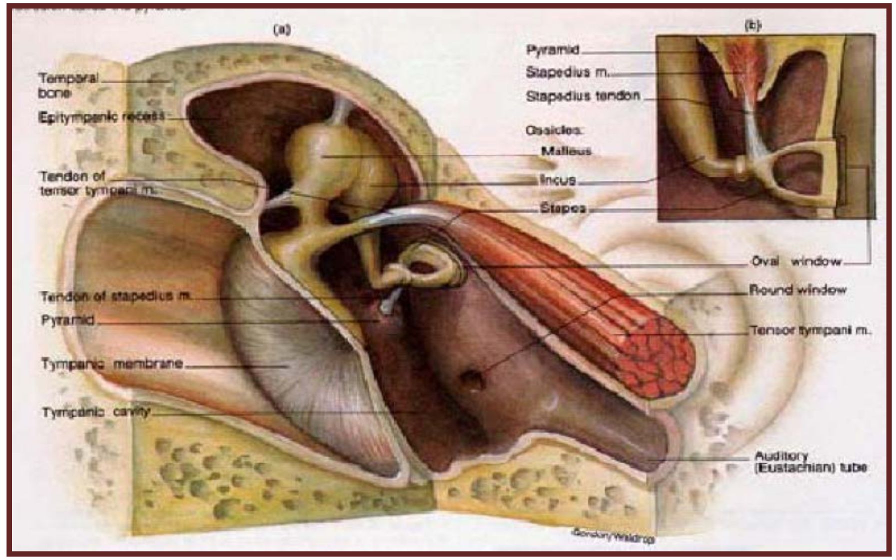
PI: William A. Ahroon, Ph.D. **Org:** The Geneva Foundation/U.S. Army Aeromedical Research Laboratory **Award Amount:** $3,081,623

Study/Product Aim(s)

- Fully document the effects of acoustic impulses on the middle ear and on middle-ear muscle contractions (MEMC)
- Determine the prevalence of the MEMC as a function of hearing sensitivity and demographic factors.
- Determine whether reflexive MEMC are pervasive among normal-hearing listeners.
- Determine whether classically-conditioned MEMC are pervasive among normal-hearing listeners.
- Determine the validity of the middle-ear assumptions of the Auditory Hazard Assessment Algorithm for the Human Ear (AHAAH)

Approach

The response of the middle ear to acoustic impulses will be measured using Wide Band Absorbance (WBA) alone and in classical conditioning paradigms.



Timeline and Cost

Activities CY	14	15	16	17	18
NHANES prevalence study					
Characterize MEMC using WBA					
MEMC classical conditioning test					
Operational evaluation of MEMC					
Estimated Budget ($3,081,623)	275.4K	804.6K	776.8K	767.3K	457.5K

Updated: 23 October 2017

Goals/Milestones

CY15 Goal – MEMC Prevalence

✓ Develop MEMC detection algorithm on NHNES impedance traces

✓ Determine the prevalence of the acoustic reflex from the NHANES data base

CY16 Goals – Wide-band Absorbance Methods

✓ Validate MEMCs using Wide-Band Absorbance

CY17 Goal – MEMC Classical Conditioning

☐ Determine form and prevalence of MEMC conditioned response

CY18 Goal – Operational Demonstration

☐ Sniper-spotter lab & field test of AHAAH middle-ear assumptions

Comments/Challenges/Issues/Concerns

- None

Budget Expenditure as of

Projected Expenditure: $3,081,623

Actual Expenditure: $1,652,461